K982509

SEP 30 1998

ATTACHMENT 9 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02154
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. **Name of the Device**

Trade Name: Ortho Implant
Common Name: Orthodontic Implant
Classification Name: Dental Implant (21 CFR 872.3640)

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI SLA Dental Implant with Bonding Base (K971578, K973353)
Nobel Biocare Onplant (K980460)
Sendax Mini Dental Implant (K972351)

4. **Description of the Device**

The Ortho implant is a solid one-piece, threaded, self-tapping design made from CP titanium, Grade 4. It is available in insertion lengths of 4.0 mm and 6.0 mm. It has the same rough surface as cleared Straumann endosseous implants. The transmucosal part has a smooth machined surface to allow for the attachment of epithelial tissue. The coronal portion of the implant is internally threaded and has a hex head.

5. **Intended Use of the Device**

The Ortho implant of the Straumann Orthosystem is an endosseous implant intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.

6. Basis for Substantial Equivalence

The Ortho implant is substantially equivalent to ITI SLA Dental Implant with Bonding Base, the Nobel Biocare Onplant, and the Sendax Mini Dental Implant in intended use, material and design.

The Ortho implant has the same intended use as the Straumann bonding base used in combination with an ITI dental implant and the Nobel Biocare Onplant. Like the Onplant and the Sendax Mini Dental Implant, the Ortho implant is intended to be used as a temporary implant.

The Ortho implant is composed of the same material and has the same surface as the ITI SLA dental implant. In addition, the design of the Ortho implant is similar to the Nobel Biocare Onplant. The implant has a rough surface in contact with bone for osseointegration and a smooth titanium surface in contact with mucosa. Both implants have a threaded transmucosal portion for attachment of the orthodontic anchorage appliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02154

Re: K982509
Trade Name: Ortho Implant and Accessories
Regulatory Class: III
Product Code: DZE
Dated: July 17, 1998
Received: July 20, 1998

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982509

Device Name: _____

Indications For Use:

The Ortho implant of the Straumann Orthosystem is an endosseous implant intended for placement in the median palatal region or in retromolar positions. Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982509

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)